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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,935	09/29/2000	Patrick Hearing	3927-4133US2	1381

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EXAMINER

WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/530,935

Applicant(s)

HEARING ET AL.

Examiner

Brian Whiteman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9,10,13-17,19,38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6 is/are allowed.
- 6) ☒ Claim(s) 1-5,9,10,13,15-17,38 is/are rejected.
- 7) ☒ Claim(s) 7,14,19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Final Rejection

Claims 1-7, 9, 10, 13-17, 19, and 38 are pending.

Applicants' traversal and the amendment filed on 3/4/03 is acknowledged and considered.

Claim Objections

Claim 7 is objected to because of the following informalities: the font is incorrect for the number 8 in the term "5'-TTGN₈CG-3' (SEQ ID NO: 1)". The font should be subscript.

In addition, applicants amended the term by changing the font of the number 8 without underlining the amendment to the term.

Appropriate correction is required.

Claims 14 and 19 are objected to for depending on a rejected claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13 and 15-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In view of amended claim 10 filed on 4/12/04, claims 13 and 15 (dependent from claim 10) introduce new subject matter into the application. The application and the originally filed claims as a whole are directed to:

13) A helper adenovirus vector comprising a packaging signal sequence consisting of at least two copies of SEQ ID NO: 1 and an A repeat VI element, wherein a repressor binding site alternates with the packaging signal sequence.

15) A helper adenovirus vector comprising a packaging signal sequence consisting of at least two copies of SEQ ID NO: 1 and an A repeat VI element and having 3-12 copies of the packaging sequence and wherein a repressor binding site is located between packaging sequences.

With respect to claim 13, as now claimed, the specification does not disclose support for a repressor binding site flanking the packaging signal sequence and a repressor binding site

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alternating with the packaging signal sequence. In addition, with respect to claim 15, as now claimed, the specification does not disclose support for a repressor binding site flanking the packaging signal sequence and a repressor binding site being located between packaging signal sequences. As set forth above, the originally filed claims provide support for a helper adenovirus vector, wherein a repressor binding site alternates with the packaging signal sequence or a repressor binding site is located between packaging signal sequences. No page is cited for support of the new limitation in claims 13 and 15 based on the amendment to claim 10. MPEP 714.02 states, "Applicant should also specifically point out the support for any amendments made to the disclosure. See MPEP § 2163.06." It is apparent that the applicants at the time the invention was made did not intend or contemplate making and/or using the helper adenovirus vector as set forth in the claims dependent from claim 10 as part of the disclosure of their invention. There is no evidence in the specification that the applicants were possession of the helper adenovirus vector as set forth in the claims 13 and 15, as they are now claimed, at the time the application was filed.

Claims 16 and 17 are also rejected under 112 first paragraph, new matter, because they are dependent on claim 15.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-5, 9, 13, 15-17, and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1-5, 9, 13, 15-17, and 38 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: regulating adenovirus packaging of a DNA delivery adenovirus. Claim 1 recites propagating the helper adenovirus vector and propagating the DNA delivery adenovirus vector, however, the claim is missing the step for propagating both vectors in the same cell line to regulate adenovirus packaging of the DNA delivery adenovirus.

Claims 2-5, 9, 13, 15-17, and 38 are also rejected under 112 second paragraph because these claims depend from claim 1.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: how the repressor binding site can flank the packaging signal sequence and alternate with the packaging signal sequence.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: how the repressor binding site can flank the packaging signal sequence and be located between packaging signal sequences.

Claims 16 and 17 are also rejected under 112 second paragraph because they are dependent on claim 15.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 10 remains rejected under 35 U.S.C. 102(b) as being anticipated by Schmid et al. (IDS, J. Virol, 71: 3375-3384, 1997) as evident by Schmid et al. (IDS, J. Virol, 72:6339-6347, 1998). Schmid teaches an adenovirus serotype 5 vector consisting of at least two copies of 5'TTTGN8CG-3' and an A repeat VI element and a repressor binding site flanking the packaging sequence (Figure 1, page 3376). The AII and AV regions of the adenovirus vector anticipate at least two copies of 5'TTTGN8CG-3'.

Schmid does not specifically teach that the adenovirus serotype 5 packaging sequence contains the COUP-TF binding site (a repressor binding site) flanking the packaging sequence. However, the COUP-TF binding site is naturally embedded in the adenovirus 5 packaging sequence as evident by Schmid (J. Virol., 72:6339-6347, 1998). Schmid reports, "We conclude that COUP-TF1, when synthesizes in vitro, displays sequence-specific binding for all minimal packaging domains" (page 6344). Other packaging domains are considered to be repressor binding sites, e.g., AI and AVII. Thus, the product taught by Schmid (1997) would anticipate the

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product in claim 10 because Schmid (1998) teaches that AI and AVII can bind to COUP-TF1 and would be considered a repressor binding site flanking AII, V, and AVI.

Applicants' arguments filed 3/4/03 have been fully considered but they are not persuasive.

Applicants argue that Schmid (1998, page 6343) report that the "AVI probe contains highly conserved dimeric consensus overlap AVI (5'-GGACTTGACC-3'); only the upper strand is indicated, with the COUP-TF half sites underlined and AVI indicated is boldface" and one skilled in the art would understand that the COUP-TF binding sites does not flank the packaging signal sequence, rather the A repeat VI element contains the COUP-TF binding site.

Applicants' argument is not found persuasive because when reading the entire article by Schmid (1998), Schmid reports, "We conclude that COUP-TF1, when synthesizes in vitro, displays sequence-specific binding for all minimal packaging domains" (page 6344). Thus, other packaging domains are considered to be repressor binding sites, e.g., AI and AVII.

Claim 10 remains rejected under 35 U.S.C. 102(a) as being anticipated by Schmid et al. (IDS, J. Virol., 72:6339-6347, 1998). Schmid teaches an adenovirus serotype 5 vector comprising a packaging signal consisting of at least two copies of 5' TTTGN8CG-3' and an A repeat VI element. (Figure 1, page 6340). The AII and AV regions of the adenovirus vector anticipate at least two copies of 5' TTTGN8CG-3'. Schmid further teaches that the adenovirus packaging element has a repressor binding site embedded in it and that the binding site interacts with COUP-TF (pages 6342-6344). Schmid reports, "We conclude that COUP-TF1, when synthesizes in vitro, displays sequence-specific binding for all minimal packaging domains"

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(page 6344). Thus, other packaging domains are considered to be repressor binding sites, e.g., AI and AVII. In addition, Schmid teaches that the adenovirus vector has a packaging sequence (AII and AV) that is flanked by the repressor-binding site, AI or AVII.

Applicants' arguments filed 3/4/03 have been fully considered but they are not persuasive because applicants provide the same arguments that were already addressed in the above 102(b) rejection.

Conclusion

Claims 6 is free of the prior art of record and claim 6 is in condition for allowance.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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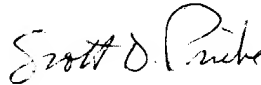
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (571) 272-0760.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
Patent Examiner, Group 1635


SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER